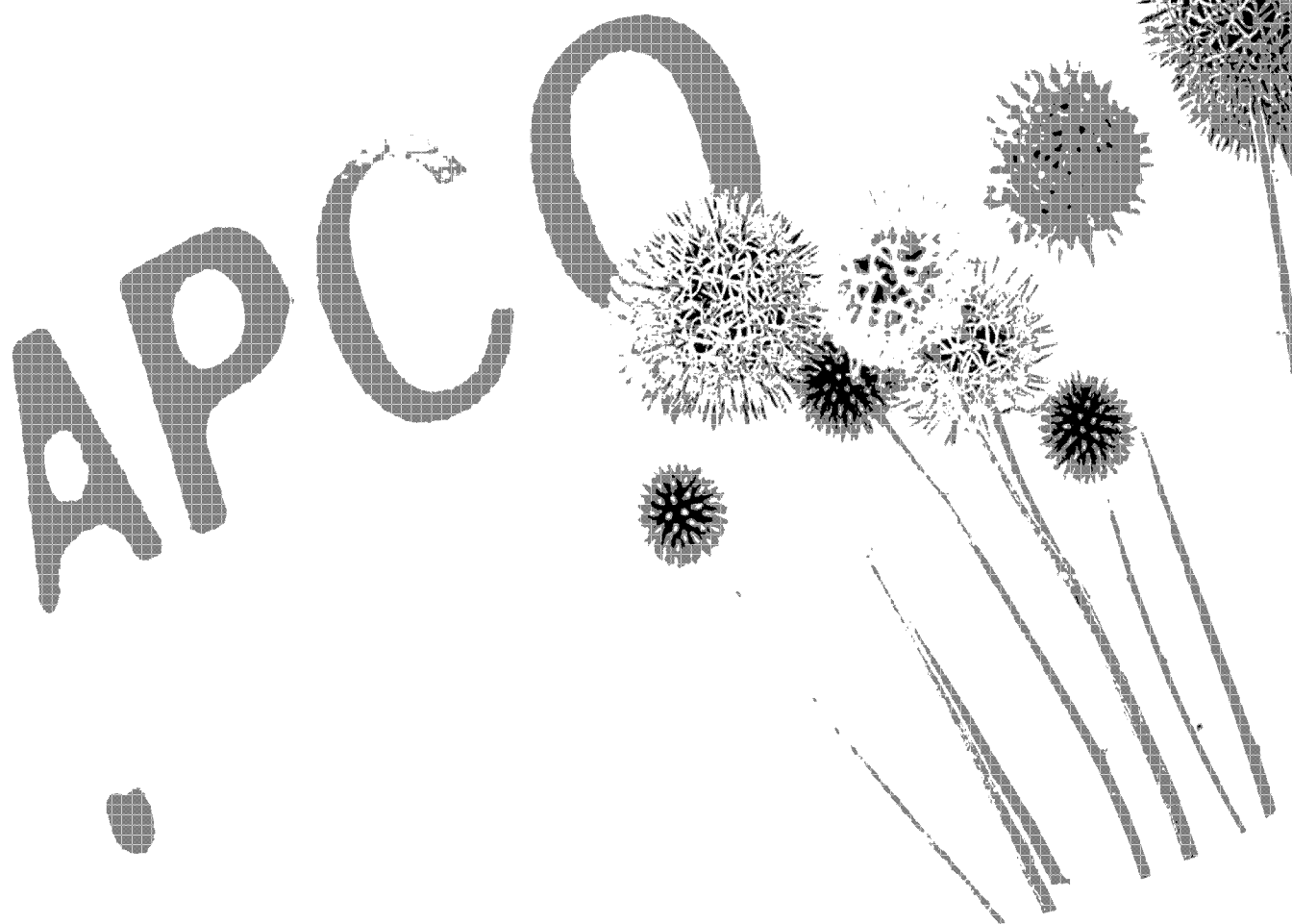


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HDMA Message Development Research: Summary of Qualitative Findings

FEBRUARY 2013

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BACKGROUND AND OBJECTIVES:

This document summarizes findings from the qualitative (focus groups and in-depth interviews) portion of the HDMA message development research program.

The overall goal of this research is to arm HDMA with resources to identify threats, mitigate risks, educate primary stakeholders and build the foundation for a leadership platform. The findings of this research will help inform the development of messages that aim to explain the industry's value in the supply chain and to the entire healthcare system, as well as address issues and expectations for HDMA/the industry to address critical issues – most specifically around diversion and prescription drug abuse.

The objective of this preliminary phase of qualitative research is not to “measure” opinion, but rather to have a robust discussion on the value of the healthcare distribution industry and key issues. These findings will inform the development of a questionnaire that will rigorously test messages to isolate those that effectively position HDMA among its key stakeholders.

AUDIENCES AND METHODOLOGY:

APCO Insight conducted focus groups and in-depth interviews among Opinion Leaders, Pharmacists, Policy Influencers and Law Enforcement. Each audience is defined as follows:

- **Opinion Leaders:** The top 10% of the most active and informed segment of the general population.
- **Pharmacists:** Specifically, those with purchase decision-making authority and responsibilities at local, chain and hospital pharmacies.
- **Policy Influencers:** Senior officials in the federal legislative and executive (regulatory) branches of government, such as Congress, FDA and ONDCP. It also includes targeted state legislative and regulatory officials (such as state boards of pharmacy) and thought leaders at relevant think tanks, nonprofits and NGOs.
- **Law Enforcement:** Practicing and retired law enforcement officials at the state and federal levels, including regulatory officials at the DEA and state attorneys general in “hot spot” states.

A summary of the scope is as follows:

AUDIENCE	APPROACH	LOCATION(S)
Opinion Leaders	3 Focus Groups (8 per group)	1 DC metro area 1 in diversion “hot zone”: Orlando, FL 1 outside diversion “hot zone”: Philadelphia, PA
Pharmacists	3 Focus Groups (8 per group)	1 DC metro area 1 in diversion “hot zone”: Orlando, FL 1 outside diversion “hot zone”: Philadelphia, PA
Policy Influencers	11 IDIs	National, with targeted interviews among officials in West Virginia
Law Enforcement	6 IDIs	

KEY FINDINGS

Industry Awareness

- There is little unaided awareness of the role of healthcare distributors in the pharmaceutical supply chain (outside of Pharmacists and State Regulators who have direct, transactional relationships with distributors). In value-neutral terms, distributors are described as the “middle-man” or link between manufacturers and the dispensers.
- The industry maintains the benefit of doubt – even if not top of mind. The supply of medicines in the US is viewed as safe, reliable and trustworthy – this evidence defines the distribution industry and serves as the criterion that establishes the industry’s essential role.

Benefits and Complexities Associated with Healthcare Distribution

- The essential role of healthcare distributors is to provide access to prescription medicines to patients who need them. To this end, the primary expectations of healthcare distributors are to maintain, reliably stock and transport prescription medicines to dispensing customers in a timely manner. The logistics and data/information management expertise of healthcare distributors are essential to meet this essential need in the healthcare system.
- Still, stakeholders describe a number of challenges the industry faces that make their day-to-day responsibilities complex. Product integrity, regulatory compliance, logistical barriers and inventory tracking are a few key issues. Of note, a cynicism emerged among stakeholders, particularly Pharmacists, about the role distributors may play in pricing and drug supply; a concern about potential manipulation that benefits from their unique, central role in the supply chain.

HDMA & Member Company Awareness

- Across stakeholder groups, there is little awareness of HDMA, with the notable exception of some Policy Influencers – mainly state and federal regulators who have had direct interactions with the association. HDMA’s function is unclear to many, but, at minimum, is expected to act as the central voice for primary distributors.
- Awareness of specific primary healthcare distributors – Cardinal Health, McKesson and AmerisourceBergen in particular – is more common. There is low (but detectable) unaided awareness of controversies facing healthcare distributors – with the notable exception of Cardinal Health in Florida.

Prescription Drug Abuse

- There is universal agreement that prescription drug abuse is a serious issue that needs to be addressed. Many describe the issue as having reached “epidemic proportions.”
- Respondents rank doctors and users as most responsible for prescription drug abuse, but also blame pharmacists, family members, pharmaceutical companies (manufacturers), the legal/regulatory structure (DEA/law enforcement), criminals/drug dealers, payers and media.
- Distributors are rarely named as responsible for the misuse crisis – even with prompting. Law Enforcement and Policy Influencers are more hesitant to assign blame to any one stakeholder in particular.
- However, there is agreement that the industry can and should play a credible and meaningful role in helping combat issues related to prescription drug abuse and drug diversion. As a central part of the pharmaceutical supply chain, healthcare distributors have a “moral obligation” to help combat the issue.

Role of Healthcare Distributors in Addressing Diversion

- At a minimum, healthcare distributors are expected to vigorously execute their core expertise: the safe, reliable and accurate delivery of medicines to dispensers. Compliance with all laws and regulations is also a minimum expectation.
- But, there is an expectation among respondents to go beyond by leveraging data to monitor for irregularities and actively share information with dispensers and law enforcement. Better use of data monitoring and reporting are threshold activities in which distributors can engage to demonstrate they are taking the issue – and their potential culpability – seriously.
- Further actions, including collaboration with key stakeholders, support of regulation development and awareness campaigns also add value.

Value Proposition

- The value proposition of healthcare distributors is unequivocal. Distributors are essential in the pharmaceutical supply chain and offer tangible benefits to society. With low levels of awareness, HDMA and its members have a rich opportunity to leverage its value to address critical challenges, such as drug diversion.
- Pharmacists, as well as Law Enforcement (local, state, associations), can be powerful allies to help amplify the industry's value proposition and work towards meaningful progress to combat issues related to prescription drug abuse and drug diversion.

INDUSTRY AWARENESS

Among Opinion Leaders, the healthcare distribution industry is not top-of-mind. Other audiences, Pharmacists and State Regulators in particular, benefit from greater awareness of the industry because they have more interaction with them. Regardless of awareness levels, impressions of the industry range from neutral to positive. And, nearly everyone interviewed is willing to give the industry the benefit of the doubt based on their view that the U.S. drug distribution system is proven as safe, reliable and trustworthy. Importantly, all recognize the central role distributors play in the healthcare supply chain, even if not top of mind.

Role of Healthcare Distributors

At the most basic level, healthcare distributors are described as providing access to prescription drugs. They exist to provide a necessary service: getting patients prescription medications when they are needed. Healthcare distributors are often described in practical terms, such as the “middle man.” More specifically, they are charged with the safe and secure transport of prescription medicines from the manufacturer to the pharmacy customer in a timely fashion. Healthcare distributors are presumed to be logistics experts.

“How much more can distributors do than transport the medicines they supply to us? How much more do we need them to do except bring us the medication so that we can then give it to the customer? There isn't really another role for them.”
– Pharmacist

However, their responsibilities extend beyond the mere transport of prescription medicines. Specifically, healthcare distributors are accountable for the integrity of the product from the time it leaves the manufacturer to when it reaches the pharmacy customer. This includes having the appropriate procedures and safeguards in place to ensure the product is not tampered with or does not become contaminated in any way, such as proper storage and temperature control. This is especially important among Pharmacists, who are keenly aware of the impact on the patient should a product not be available due to improper handling or other distribution-related issues.

“They keep the drug supply safe and plentiful by ensuring the supply of drugs gets to the destination where it's needed while making sure that the drug supply is stable and kept at the optimum storage conditions.”
– Opinion Leader

Among Policy Influencers and Law Enforcement, there are heightened expectations for healthcare distributors to ensure the security of the medicines being transported, specifically to minimize any potential for diversion.

Pharmacists rely on healthcare distributors to keep the medicines they need in stock and work with them directly to ensure they have adequate supply to meet patient demand. Accuracy in orders is a frequently mentioned expectation among Pharmacists; this assures they can abide by one of the basic tenets of healthcare delivery: dispensing the right medication, at the right dose, in the right form, to the right patient and at the right time. To be clear, it is not just meeting supply needs but also helping them better anticipate needs. Pharmacists perceive that distributors maintain vast data/information technology to help with predictions for seasonal or supply availability trends.

“They are responsible for getting the drug from point A to point B, keeping track of what drugs they have and making certain that those drugs are protected so that it's not diverted.”
– Policy Influencer

Benefits of Healthcare Distributors

Although the industry is not particularly top-of-mind, prompted conversations reveal a wide-range of benefits. Many evoke strong words to describe the value of the industry, which are generally positive and connect to the efficiencies distributors offer. They are “experts” in healthcare distribution, have “privileged access” to prescription medications and are the “guardians of the drug supply.” While Opinion Leaders needed some prompting, Pharmacists, Policy Influencers and Law Enforcement are quick to name a plethora of benefits the industry offers.

BENEFITS OF HEALTHCARE DISTRIBUTORS	<p><u>Efficiencies/Economies of Scale:</u></p> <p>Due to their size and reach, distributors are often credited with making the process of accessing prescription medicines quick and seamless. Pharmacists often refer to their distributors as “one-stop shops.” In addition to providing access to prescription drugs, distributors often stock medical supplies and personal care items that can be purchased directly through the distributor at value pricing.</p>	<p><u>Specialization:</u></p> <p>Distributors allow manufacturers and pharmacies to focus on their jobs without having to worry about the logistics. Through the use of distributors, time, money and resources are efficiently utilized throughout the supply chain. For manufacturers, this means being focused on drug discovery and development; pharmacists can spend more time with patients.</p>
	<p><u>Logistics Management:</u></p> <p>Healthcare distributors are credited for being experts in what they do best: logistics. From dealing with the manufacturers, to receiving and filling orders, to maintaining proper storage and handling, to safely and securely delivering the products to the pharmacy, healthcare distributors are seen as specialists in their field. The centralization of distribution (as opposed to having every manufacturer handle distribution) is perceived to offer significant cost savings.</p>	<p><u>Security/Oversight:</u></p> <p>Healthcare distributors are seen as experts in security. At a threshold level, this means maintaining the physical security of their warehouses and trucks. In addition, distributors play a unique role in monitoring their sales to detect any suspicious ordering. Healthcare distributors are presumed to have access to the data, which is of particular importance to Law Enforcement, who think distributors can play a meaningful role in detecting potential diversion in the supply chain.</p>
	<p><u>Emergency Preparedness:</u></p> <p>Given both the recent shortage of flu vaccines and the impacts of Hurricane Sandy, being prepared for emergencies is top-of-mind. Distributors are expected to have contingency plans in place in the event of a medical crisis or other unforeseen events that can disrupt the normal supply chain. Law Enforcement, who are often on the ground responding to natural disasters, are particularly focused on this theme. Distributors are expected to work hand-in-hand with Law Enforcement to get the medicines and supplies to the patients who need them.</p>	

Issues/Complexities Facing Healthcare Distributors

While connotations are generally positive and connect to the efficiencies distributors offer, a variety of issues and complexities that can hinder distributors from operating effectively and efficiently are identified. Respondents are all too aware that if something goes awry, there are real life consequences for the patients who need to get their prescription medicines.

COMPLEXITIES FACING HEALTHCARE DISTRIBUTORS	<p><u>Pricing and Supply Manipulation:</u></p> <p>Some cynically perceive that distributors are able to reign over pricing and drug supply due to their unique, central role. This is especially true among Opinion Leaders, who tend to question the ethics of large companies' profit motives.</p>	<p><u>Shortages:</u></p> <p>Drug shortages were among the leading issues for Opinion Leaders and Pharmacists. Having an adequate supply of medicines is important because patient safety can be affected if they cannot get the medicines they need when they need them.</p>
	<p><u>Storage and Handling:</u></p> <p>Storage and handling of prescription medicines is a prominent concern among Opinion Leaders and Pharmacists. Healthcare distributors are expected to take all necessary precautions to make sure prescription drugs are stored and handled properly so that when it reaches the pharmacy, the integrity of the product is preserved.</p>	<p><u>Timely and Accurate Delivery:</u></p> <p>Even if prescription drugs are stored and handled properly, there is a concern that something could affect the actual transport or delivery of these medicines, such as employees going on strike. In turn, this affects Pharmacists' ability to provide patients with the medicines they need when they need them.</p>
	<p><u>Security:</u></p> <p>Security is a paramount concern across all stakeholder audiences – especially regarding controlled substances. Healthcare distributors are expected to maintain tight physical security of their facilities and their trucks to prevent any potential diversion – especially from theft. In addition, healthcare distributors are expected to maintain security by conducting thorough background checks on their employees.</p>	<p><u>Regulatory Compliance (Controlled Substances):</u></p> <p>Stringent regulations on controlled substances are another complexity healthcare distributors face. Regulations control every point of contact with a controlled substance – from the way they are handled and transported to how they are disposed of. They are often described as “onerous” but “necessary” to ensure security.</p>
	<p><u>Pedigree/Traceability:</u></p> <p>Being able to track inventory throughout the supply chain is another complexity healthcare distributors must address. In theory, the more people that come in contact with each order, the greater chance that something could go awry, such as diversion. Therefore, the ability to trace prescription drugs throughout the supply chain becomes of paramount importance. Although each state has their own pedigree regulations, healthcare distributors are expected to work within each framework to ensure a safe and secure supply chain – keeping counterfeit and diverted products out, while maintaining an efficient distribution system for legitimate prescription drugs.</p>	

U.S. Prescription Drug Distribution System Largely Seen as Safe and Reliable

On the whole, respondents believe that the U.S. drug distribution system is safe and reliable. Opinion Leaders readily admit that they have not given this much thought. Therefore, the criterion upon which they base this assumption is usually whether or not their prescription medicines are available to them when they need them. If they are, they tend to believe the system is working properly.

"The general public trusts the system and assumes that it is taken care of. Until there's a major breach, they're going to continue to trust the system. It's going to take an incident to have people question, 'Well, wait a minute. What's going on here?'"
– Policy Influencer

For others, there has never been a reason for them not to trust the prescription drug distribution system. Should something happen that would prevent them from obtaining their prescription medicines when they needed them, they would reconsider.

On some level, respondents concede that they have to trust the system because they aren't familiar enough with the processes and procedures in place to ensure safe and reliable prescription drug distribution. This is especially pronounced among Opinion Leaders and Pharmacists.

"I have no reason to believe it's not. It seems like a system that works pretty well, that most of the abuse of the system comes at the user end. I haven't read anything to suggest that the system is not working."
– Law Enforcement

Policy Influencers and Opinion Leaders are keen to compare the U.S. prescription drug distribution system with that of other countries. To them, the United States is the safest, most reliable, and trustworthy system in the world, due to the high standards and regulations various stakeholders in the supply chain must adhere to. This is in stark contrast to developing countries, where corruption and fraud is commonplace, and laws and regulations governing distribution are either non-existent, not adhered to or

not enforced.

Others trust that the system is safe and reliable because they believe the distributors have too much at stake (financially and legally) to become careless.

"We have the gold standard because we have the strongest requirements of anywhere in the world."
– Policy Influencer

Even though most believe that the prescription drug distribution system in the U.S. is safe and reliable, respondents recognize that mistakes happen and processes can always be improved. This is most salient among Law Enforcement and Policy Influencers, who have a deeper understanding of how the distribution system works and the laws and regulations distributors must adhere to.

Having been on the receiving end of the distribution system, Pharmacists are quick to point out improvements to the system. They believe innovations in supply chain management technologies and software have helped contribute to a safer, more reliable prescription drug distribution system, and give the industry credit for helping improve the process.

AWARENESS OF HDMA AND MEMBERS

Across stakeholder groups, there is little awareness of HDMA, with the notable exception of some Policy Influencers (mainly state and federal regulators) who have had direct interactions with the association. With the exception of former DEA officials, Law Enforcement are largely unaware of HDMA.

Most understand the primary role of an industry association is to share knowledge among its member companies, to help establish industry best practices – and, generally, work toward improving the industry's actions and image. Some believe HDMA is primarily a lobbying entity. Organizing conferences and meetings, as well as publishing newsletters and educational materials are the mainstay of industry associations. It is important to note that many expect HDMA to have a governance role; establishing standards and guidelines that regulate the actions of distributors is presumed to be a role of HDMA.

With prompting, there is a call for HDMA to become a more prominent, visible representative for the industry and its key issues – especially to media (to reach the public) and directly to policymakers and regulators. Specifically, they are expected to amplify the messages most important to its members and act as the voice of industry.

Awareness of member companies, on the other hand, is more common. Pharmacists, who deal directly with distributors, have strong awareness of member companies – most notably the “Big Three”: Cardinal Health, McKesson and AmerisourceBergen.

Among Opinion Leaders, only a few had unaided awareness of news coverage about any of the distributors, which, with greater or lesser specificity, was usually related to the DEA charges against Cardinal Health in Florida. Pharmacists, Law Enforcement and Policy Influencers have more intimate knowledge of the media reports – and cite instances across the country where healthcare distributors have been in the news, including situations in Florida, West Virginia, Kentucky and North Carolina.

Sometimes, the issue is described by respondents pejoratively as “Oxycodone Express.” Indeed, there is an undercurrent of skepticism directed toward distributors – especially the case with Cardinal Health in Florida.

PRESCRIPTION DRUG ABUSE

A Problem of Epidemic Proportions

There is universal agreement that prescription drug abuse is a serious issue that needs to be addressed. Prescription drug abuse is described as a critical social issue of epidemic proportions. Respondents believe the impact of prescription drug abuse (pain medication, specifically) is “devastating our nation.” Several respondents referred to recent CDC statistics that cite more people are dying from prescription pain medication overdoses than car accidents. Indeed, with widespread impact, it is understandable that prescription drug abuse strikes an emotional chord and even directly impacts the stakeholders in the study.

*“Having been specifically involved in narcotic enforcement for over 25 years, I would safely say that right now it is probably the **fastest growing drug problem that we currently have and perhaps the most significant drug problem that we have in the United States right now.**”*
– Law Enforcement

*“I always knew this was going to happen. I’m just kind of surprised it’s happening now where there are all these shortages of the maintenance narcotic opioids. We just can’t get them. I can name three drugs here now that are fast movers that I just can’t get. **What are you going to tell the cancer people?**”*
– Pharmacist

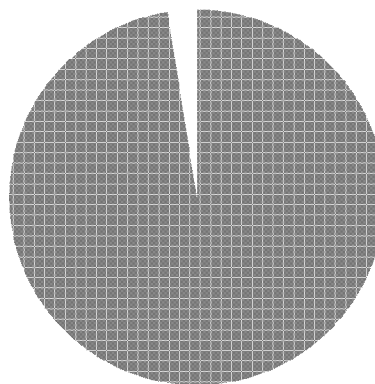
While the issue is seen as important in all markets, the impact is most acute in diversion “hot zones,” such as Florida, West Virginia and Kentucky.

Many believe a large majority of prescription pain medication sales are going to addicts. This, in turn, reduces the availability of prescription pain medicines for patients who have a legitimate medical need. The resultant shortages (or under-treatment) exacerbate the public health crisis.

Patients with medical necessity are unable to get the pain medications they need – and this strikes a particularly emotional tone when considering oncology patients.

Who's to Blame?

Who is most responsible for prescription drug abuse in the United States?*



*Focus group respondents only;
Distributors not ranked as “most responsible”

Generally speaking, respondents rank doctors and users as most responsible for prescription drug abuse, but also blame pharmacists, family members, pharmaceutical companies (manufacturers), the legal/regulatory structure (DEA/law enforcement), criminals/drug dealers, payers and media. Distributors are rarely named as responsible for the misuse crisis – even with prompting. Law Enforcement and Policy Influencers are more

hesitant to assign blame to any one stakeholder in particular. Instead, they believe that everyone in the pharmaceutical supply chain has a shared responsibility to help address this issue.

PARTIES' ROLES/RESPONSIBILITIES REGARDING PRESCRIPTION DRUG ABUSE		
Doctors/Prescribers	<p>Over-prescribing, prescribing when there is no legitimate medical need and exchanging prescriptions for money are a few reasons doctors are blamed.</p> <p>Pharmacists and Law Enforcement are especially skeptical of doctors' profit motive; described as "benignly ignorant."</p>	<p>"We have the doctors who do not know how to say no. The doctors understand the pharmacology of the drugs; they don't think about the history of that patient that they're prescribing to. Is there a history of chemical abuse in the family? Is there a genetic predisposition?"</p> <p>– Law Enforcement</p>
Users	<p>Users are often blamed for perpetuating the cycle of prescription drug abuse; personal responsibility is a pervasive theme. Users, who are often times addicted to pain medications, will "doctor shop" if another provider refuses to give them a new prescription.</p>	<p>"In the end, it's the individual who ultimately makes the decision on whether to take the meds or not. You need to put some responsibility back on the person."</p> <p>– Policy Influencer</p>
Pharmacies	<p>Pharmacists are blamed for turning a blind eye to suspicious prescriptions. However, the role of the pharmacist in mitigating diversion is unclear to many. On one hand, their job is to fill prescriptions under the assumption that the patient has seen a doctor and has a legitimate medical need for the medicine. Others expect pharmacists to exercise a level of professional judgment when filling orders.</p>	<p>"They don't have the responsibility. If the doctor writes the prescription, they're under obligation to honor it. Their job isn't to question that. If my doctor writes me a prescription, what right do they have to question it?"</p> <p>– Law Enforcement</p>
Family Members	<p>Respondents describe scenarios where family members steal prescription medicines from their relatives' medicine cabinets; youth are implicated for hosting "pill parties." Although family members are usually not the ones actively distributing the medicines, they have a responsibility to ensure their security.</p>	<p>"According to national surveys, most get their pain meds from legitimate prescriptions. Either their own, their friends, or families' prescriptions."</p> <p>– Policy Influencer</p>
Society	<p>Policy Influencers and Law Enforcement are hesitant to assign blame to a single individual or entity. Instead, they largely believe that there is a shared responsibility to help address the issues of prescription drug abuse and diversion.</p>	<p>"I don't know why we're looking to blame or point a finger. That doesn't accomplish anything. What we need to say is who are the people that can solve this and how do we work together to get it resolved, not who's to blame. And we're always looking for a silver bullet and there isn't one. Multi-disciplinary, multi-level, multi-industry cooperation has to be used to solve this."</p> <p>– Policy Influencer</p>

Government	Policy Influencers and Law Enforcement are the most likely to place some level of blame on the government. Issues related to prescription drug abuse and diversion are seen as touching all levels and areas of government, including local, state and federal law enforcement, regulators and legislators.	<p>"There's a responsibility in law enforcement. This has been a growing issue that people have been aware of for a long period of time but did not choose to focus the amount of resources that should've been focused on this."</p> <p>– Law Enforcement</p>
Pharmaceutical Companies	Many are skeptical of pharmaceutical company's profit motive, and blame them for creating a demand for pain medications, as well as making medicines with addictive properties. Others believe their marketing and advertising encourages people to seek out pain medications when they might not have a legitimate medical need.	<p>"The pharmaceutical industry shares a responsibility in not having researched the addictive potential, underselling the addictive potential, covering up the addictive potential, and not providing information to consumers about that. Also, not exploring alternative non-addictive solutions."</p> <p>– Policy Influencer</p>
Distributors	Many rebuff criticism directed towards the distributors on the grounds that the industry merely acts in logistics, but cannot control the inappropriate use of pain medications. Pharmacists, in particular, empathize with the distributors as they are doing their job to fulfill an essential need. Those who do place blame on distributors still consider them low on their list in terms of culpability. The blame is usually the result of something gone awry in the distribution process – such as failure to detect suspicious orders or theft.	<p>"That's crazy. It's like they're suing the distributors for people's prescription drug abuse. That's like suing McDonald's for people's cholesterol problems."</p> <p>– Opinion Leader</p> <p>"They're not directly responsible. They're doing what they were asked to do. They just provide the medication."</p> <p>– Pharmacist</p>

PRESCRIPTION DRUG DIVERSION

Reactions to Media Reports

Respondents were presented a summary of two recent media reports in which distributors were facing scrutiny from law enforcement for contributing to prescription drug diversion in Florida and West Virginia. Respondents have mixed views as to whether or not they think the DEA and West Virginia Attorney General were acting in a fair and reasonable manner.

Some think distributors should be held responsible and should have, in good faith, reported any suspicious ordering to the dispensers or law enforcement. Opinion Leaders, and to an extent, Policy Influencers, are particularly skeptical of the distributors in these two cases based on a presumption that they turned a blind eye for the benefit of profits.

However, most believe that multiple stakeholders in the pharmaceutical supply chain should be held accountable, not just the distributors. Among these respondents, there is more sympathy for the distributors and a willingness to extend the benefit of doubt. To paraphrase one respondent, *"The DEA is looking for someone to blame. You look at the distributors because you don't know who else to look at."* Once again, respondents stress that assigning blame for prescription drug abuse is not a "one size fits all" judgment.

"I really don't see a distributor responsible in any way for anything that's going on. I think they just take orders and they ship it out. It's doctors and users who are responsible for this problem."
— Opinion Leader

For some, distributors are not accountable because their sole responsibility is perceived as taking orders and delivering them to pharmacies. Therefore, it is not the role of the distributors to police their customers or question a doctor's medical judgment.

Policy Influencers have mixed feelings about the media reports. Regulators, who have intimate knowledge of how distributors operate, tend to agree that the distributors should have recognized the uptick in sales and side with the DEA and Attorney General. There is an expectation that distributors conduct "due

diligence" to monitor trends. Regardless of whether Policy Influencers agree with law enforcement's response, they do believe that distributors and law enforcement need to come together to talk about these issues rather than pointing blame at each other.

Interestingly, a handful of Law Enforcement side with the distributors because they do not trust the DEA. One quote, in particular, illustrates the animosity directed toward the DEA:

"As a career law enforcement executive, I can tell you I don't agree with that. The distributor's job is to distribute that drug legally from the manufacturer to a pharmacy. The distributor's job is to transport and distribute that pharmaceutical from the company who makes it to the company who sells it. It's not their job to police the company who sells it."
— Law Enforcement

"No it's not fair or reasonable. I told you before they're useless, they're politically-run, their biases and incompetence is incredible. I know how the DEA operates and I know how those distributors you just talked about operate. And it doesn't make sense to me and therefore I certainly don't swallow it as the truth. But I'm guessing many, many people do because you don't know any better."
— Law Enforcement

Expectations for HDMA and the Industry to Address Drug Diversion

Regardless of whether or not stakeholders think distributors are to blame for prescription drug abuse/diversion, they do think that distributors can play a credible role in helping combat the issue. At a minimum, distributors are expected to strictly follow all laws and regulations. However, there is a greater expectation – a “moral obligation” -- to go beyond what is expected by law to play a meaningful role as a critical member of the pharmaceutical supply chain.

“They can play a credible role in helping solve the problem based on what’s being said here. They’re trying to become better corporate citizens and take an active role in making sure it doesn’t happen again.”
– Opinion Leader

Pharmacists are particularly emphatic that the distributors need to play a role in addressing the issue. If the distribution industry were to crumble under attack, it impacts the public health: getting medicines to pharmacies to be dispensed to patients that need them, controlled substances or otherwise.

However, many see a much bigger role for distributors to play beyond mere compliance. Focus group participants were offered a list of proposed solutions. Among those most important for HDMA and the industry to consider are: drafting more specific regulations, access to DEA volume data and increased oversight of prescribers/dispensers. On the other hand, solutions that were initially viewed as less important among the focus group participants included, promoting greater use of e-prescribing, building partnerships and leveraging states’ role as regulators.

Proposed Solutions (ratings from focus group participants only)	% Top Three	% Bottom Three
Drafting more specific regulation with the DEA regarding suspicious order detection and monitoring (quotas/directions)	59%	13%
Sharing of DEA volume data with distributors and/or state regulators	53%	3%
Increasing oversight of pain clinics, online pharmacies and/or "pill mills"	47%	9%
Making better use of prescription drug monitoring programs	41%	-
Establishing a cross agency (FDA and DEA) advisory group	38%	13%
Promoting public education about prescription drug abuse	28%	22%
Enhancing enforcement efforts to address online pharmacies and "pill mills"	19%	16%
Increasing funds for enforcement, such as increased inspection capabilities or updated registration requirements	13%	13%
Ensuring proper disposal of prescription drugs	9%	19%
Promoting e-prescribing for controlled substances	9%	34%
Building partnerships among key stakeholders	3%	22%
Leveraging the state's role as regulator and purchaser of services	3%	25%

The prompted exercise lead to robust conversations about solutions HDMA and the industry can consider to address drug diversion. Similar, unprompted, conversations unfolded in the in-depth interviews. The findings can be summarized in the following key areas: Data Monitoring/Oversight, Reporting, Regulating, Convening and Educating.

- **Monitoring:** Distributors have a privileged view of prescription drug orders. As such, there is a minimum expectation to conduct due diligence for irregularities in order volume. Indeed, the distributors' role in monitoring volume trends is the key to their culpability – or not. Not only do distributors have the data, they also are perceived to have the latest technology and software to analyze data. Individual member companies have an obligation to continuously monitor trends. Going a step further, many believe HDMA can play a central role in monitoring data compiled from individual member companies. Aggregating data would allow HDMA to identify outliers across wide geographic areas, even nationally.

*"The thing distributors have that no one else has in that equation is the **visibility of everything**. Because the manufacturer can't see what other manufacturers are delivering, and a pharmacy only sees what a pharmacy has and doctor only sees scripts he makes. So, **the distributor's the only one that has the information access.**"*
– Opinion Leader

A few Policy Influencers suggest making better use of prescription drug monitoring programs. Compiling distributors' order data and cross-referencing it with filled orders (from PMPs) could act as an "early-warning surveillance tool" to try to identify emerging trends and issues with controlled substances across the country.

- **Report:** Data monitoring for irregularities is insufficient if action does not follow. The obligation of the industry is to report (to pharmacies or DEA) when misconduct is identified in data trends. In fact, many assume that the industry is already actively reporting on suspicious orders, with the media reports being more the exception than reality. Policy Influencers, in particular, assume HDMA must already have a national database that aggregates sales data from member companies. Notably, the reporting expectation goes beyond diversion to also address potential shortages or surges.

*"Pledge to work with their customers, the **DEA** and the states to gather and report information about unusual numbers of requests for particular drugs. And also to pledge to work with the DEA and the states to develop rules and regulations for the reporting of the unusual numbers of requests for particular drugs."*
– Opinion Leader

*"They're in a **unique position to grab data**. That no other part in the supply chain from the real manufacturers to the addicts can get. So **because they have the unique ability to get this data, they have a responsibility. To show good faith, to show response, to show that they're interested in addressing this problem, they need to share that data.**"*
– Opinion Leader

- **Regulate:** There is a belief (particularly among Pharmacists) that there are unclear or non-existent guidelines regarding the appropriate use of data and reporting requirements. HDMA is expected to play a role to inform such regulations. Plainly stated by an Opinion Leader: *"If the DEA is going to hold distributors responsible (for prescription drug diversion), they should at least have a say in the guidelines that direct their business."* In addition, working with the DEA to draft more specific regulations regarding suspicious order detection and monitoring is seen as a positive step towards mending a tumultuous relationship between DEA and distributors.

"It seems unclear what everybody's expectations are. I feel something like drafting more specific regulation with the DEA would be helpful. That way, each area knows what they are responsible for. If they do see certain changes, then they know that they have to do that." – Pharmacist

Additionally, a handful of state regulators mentioned they would like to see the industry advocating for a consistent, national framework to track and trace medicines throughout the supply chain. Achieving a national framework means that everyone is held to the same standard – and makes identifying the point at which diversion may occur much easier.

- **Convene and Collaborate:** The central role of the distributors – between manufacturers and dispensers and aligned with law enforcement/regulators – makes HDMA well suited to bring together diverse players to work toward progress. Policy Influencers and Law Enforcement are particularly fond of building relationships with HDMA and its member companies to help combat the issue of prescription drug abuse. In several interviews, respondents urged HDMA to contact them to brainstorm ways to collaborate. Even more, many imagine the DEA and distributors would have a tenuous relationship. Therefore, building

"What they need to do is take actions that, at least symbolically, demonstrate that they're making a good-faith effort. There are a number of interested and concerned parties: the DEA is one, the Office of National Drug Control Policy is another, the Department of Justice is one, and so is the Department of Health and Human Services. If I were a distributor, I wouldn't want to just be responding to one of these agencies, like the DEA. I would want to have these agencies reach some kind of consensus about what should be done."
– Policy Influencer

relationships with key stakeholders other than the DEA is seen as having a two-fold benefit: creating allies for HDMA and its members, and working together to address prescription drug abuse and diversion.

Among Law Enforcement, the expectation is to build better relationships with state and local law enforcement, who are the ones on the ground combating the issue every day. Focus group participants, who were given a list of proposed solutions for the industry, are fond of establishing a cross-agency (such as FDA and DEA) advisory group.

"The first thing is to create an agency that's not them. It could include them, but it's not them. So, maybe it's some people from DEA, some people from FDA, and some people from the actual distributors themselves, so you have a very balanced group. But I don't think that you can really accomplish anything on this list until you have that created."
– Opinion Leader

"I would start a coalition group of physicians, hospitals, pharmacies and pharmaceutical companies and distributors and have an entire education campaign about how prescription painkillers are killing people because of abuse. I would work with legislators to get out in front of this major issue."
– Policy Influencer

- **Educate:** HDMA can act as educator to inform key audiences, including the public, about issues (including specific to prescription drug misuse) or even the role of the industry in providing a safe, reliable supply. Law Enforcement and Policy Influencers are particularly keen on the idea of partnering with HDMA to promote public education about prescription drug abuse. Opinion Leaders welcome the idea of public awareness campaigns, but ultimately aren't convinced they would have much impact on the prescription drug abuse problem. Policy Influencers, in particular, see an important role for HDMA in educating stakeholders about how the industry works to ensure a safe and reliable supply. Education is seen as important to articulate the value of the industry and correct misperceptions about potential misconduct.

*"I want to know **what they're doing to educate the public**, and by the public I mean those who are most susceptible to drug abuse, about the risks of abusing drugs, about the consequences for mixing painkillers with alcohol."
— Policy Influencer*

INDUSTRY MESSAGES

Respondents were presented with a series of messages drafted by HDMA in response to recent events in Florida and West Virginia. Respondents tend to be receptive to the message points; the views can be described as neutral to positive. The facts that are presented are believed to be true and respondents perceive the industry to be “frustrated” with the accusations given the realities of their operating environment.

*“So, ultimately, they
become the fall guy.”
– Opinion Leader*

A clear message that is delivered through the existing messages is that the industry has limited access to data from DEA. And, importantly, without such access, respondents are sympathetic to HDMA and the industry and question how distributors can be held responsible for diversion. Described as an “information shortage” by a Policy Influencer, the messages have the effect of seeding doubt about regulators/enforcers.

*“The DEA not providing access to aggregated blinded data is classic, and I can always tell you the answer, they’re not going to do it. You know some of it is based on incompetence, and I’m really serious with this, gross incompetence of the agency. They look at all the DEA registrants, especially distributors and manufacturers, as the enemy. They’re incompetent and I know it’s very frustrating. And instead of having an open exchange and looking at distributors and manufacturers as people to collaborate with, they don’t do anything.”
– Law Enforcement*

Among Law Enforcement, there is first-hand recognition of the challenges collaborating with DEA. Indeed, as described by one Law Enforcement respondent, DEA is considered a “one-way street” when it comes to information sharing. These respondents are sensitive to messages concerning limited access to aggregated blinded data. And, moreover, they are wary of larger-scale implications related to access to additional data – directly stated, the possible “slippery slope” of reporting expectations.

However, some skepticism emerges among stakeholders about the centralizing role that HDMA does (or does not) play. Among Opinion Leaders and Pharmacists, in particular, there is a perception that HDMA is unaware of member company activity to prevent diversion; these stakeholders expect the industry to collectively accept more accountability. As the representative of the industry, HDMA is expected to monitor its members and share critical information. Without regard to anti-competitive practices, these stakeholders have a foundational expectation that the industry is collaborating to address diversion.

Even though respondents, by and large, understand and agree with the rationale behind these messages, the statements run the risk of coming across as too defensive and can potentially harm credibility. The messages must convey that HDMA and the industry accept responsibility for addressing the diversion issue.

*"It's more about what they **can't do** than what they **can do** in this."
– Pharmacist*

*"It seems like **HDMA** is kind of washing their hands from this responsibility that they have any accountability."
– Pharmacist*

So, while it is compelling that distributors have limitations on access to information and that there are challenges in collaboration with DEA, it does not excuse inaction. Indeed, while little regard is given to the DEA, there remains an expectation for HDMA and the industry to establish that it has been doing the right thing all along. And, there is an expectation that HDMA and the industry should reinforce it takes the issue seriously and will go beyond what is currently expected by law to combat diversion and drug misuse.

*"HDMA should say **because we are in the center, let's do something about this. Let's not wait until this becomes more of an epidemic. They should step up to the plate.**"
– Pharmacist*

Importantly, stakeholders believe the industry has the opportunity to describe the current actions they take to monitor and report distribution anomalies and should be more proactive in their communications. In particular, having developed industry compliance guidelines in advance of DEA clarifying their expectations is seen as a positive, proactive message.

To be clear, HDMA must first communicate what they and the industry already do then layer information about constraints placed upon them. It is important to remember that drug diversion/pain medication abuse is a highly emotional issue for which all are responsible to address.

VALUE PROPOSITION

At the conclusion of each conversation, stakeholders were asked to describe the most important benefit or value the industry provides to society. Notably, this question was asked directly following a detailed examination of the drug diversion issue and the industry's role. Respondents refer back to positive attributions of the healthcare distributor's essential role in the pharmaceutical supply chain: providing access to prescription medicines. The industry's value proposition is clearly and consistently articulated across all stakeholders groups, and is described in the following ways:

"The single most important value of the industry is distribution of medication that we all need for our lives. If they weren't there, I don't know how we'd get it."
-- Opinion Leader

- Maintaining a robust and safe supply of prescription medicines;
- Making prescription medicines available as they are needed; and,
- Safe, reliable and timely delivery of prescription medicines and healthcare supplies.

"The single biggest thing that they can provide to society is to make sure that prescription drugs are going to the people who need them safely, quickly and are not ending up in the hands of people who should not be using them or use them incorrectly."
-- Policy Influencer

Indeed, stakeholders believe distributors meet, and to some extent, exceed these expectations. This offers distributors a bank of goodwill that can be leveraged to clarify their role in assuring safe, reliable and accurate distribution of controlled medicines. Because prescription medicines are largely available to patients when they need them, many freely admit that they tend to take the healthcare distribution industry for granted. In other words, without distributors, prescription medicines would not get to patients that need them, which in turn can affect patient outcomes.

Of note, Pharmacists and Law Enforcement (state, local, associations), can play a meaningful role in amplifying the industry's value proposition. They are most likely to give distributors the benefit of the doubt and understand the complexities of the supply chain.

Pharmacists, as those operating on the front lines of healthcare delivery, are all too familiar with the risks to the patient should something interrupt the delivery of prescription medicines. At the end of the day, pharmacists depend on distributors to dispense medicines to patients. Therefore, pharmacists can play the role of a vocal advocate for the industry.